Remarks

By the present Amendment, claim 1 has been cancelled, and claims 2, 3, 5-10, 11, 13, 14, 18, and 19 amended. Claim 128 is newly presented for consideration. Various amendments have also been made to the specification. Accordingly, claims 2-15, 18-30, and 128 are now pending in the application.

In the Office Action of September 11, 2004, claims 1-15 and 18-30 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. Claims 1-15 and 18-30 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The cancellation of claim 1 renders some of these grounds of rejection moot. With respect to the remaining claims, these rejections are respectfully traversed.

Applicants would like to thank the Examiner for the withdrawal of the species election requirements regarding the invention of Group I.

I. Support for Claim Amendments

Claim 128 has been added to more clearly define the invention by addressing, at least in part, some of the issues raised in the Office Action. Claims 2, 3, 5-10, 11, 13, 14, 18, and 19 have also been amended to address issues of indefiniteness raised in the Office Action. Applicants respectfully submit that the amended claims are fully supported by the specification. Accordingly, no new matter is added by this Amendment and entry thereof is respectfully requested.

II. Sequence Rule Non-Compliance

The specification has been amended to include the corresponding sequence identification numbers cited along with each sequence in the specification on page 45, line 12. Moreover, the paragraph beginning at page 46, line 11 ([0156]) and Table 10 have been amended to include the sequence and corresponding sequence identification numbers, as suggested by the Examiner. Accordingly, no new matter is added by this Amendment and entry thereof is respectfully

requested. Nonetheless, Applicants respectfully point out that sequences fewer than four specifically defined nucleotides or amino acids are excluded from this requirement under 37 C.F.R. § 1.821(a). Accordingly, the sequences at page 45, paragraphs 2 and 3 ([0152] and [0153]) were not included in the sequence listing. Substitute sheets of the "Sequence Listing" and a substitute copy of the computer readable form including all previously submitted data SEQ ID NOS: 48 and 49 are submitted together with the present Amendment. Applicants respectfully submit that the substitute sheets include no new matter and are fully supported by the original specification. The copy in computer readable form is the same as the substitute copy of the "Sequence Listing" and includes no new matter.

III. Rejection under 35 U.S.C. § 101

Claims 1-15 and 18-30 were rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter. The Examiner states that the instant claims do not require performance of a result outside of a computer. The Examiner further states that claim 1 cites the measuring of first indicia that is deemed a data manipulation step as its general embodiment that performs determination and identification without any requirements of physical action or movement cited in the claims. In addition, the Examiner states that in claims 1-15 and 18-30 no tangible physical transformation apparent.

Applicants respectfully disagree with these assertions and submit that the claims are indeed statutory under 35 U.S.C. §101.

For a claim to be statutory under 35 U.S.C. §101, "a claimed computer-related process must either: (A)... or (B) be limited to a practical application within the technological arts. ... It is necessary for the claimed invention taken as a whole to produce a practical application if there is only a transformation of signals or data inside a computer or if a process merely manipulates concepts or converts one set of numbers into another." M.P.E.P. §2106, Part IV, subpart B(2)(b) The Office Action does not suggest that the claimed invention was considered as a whole. According to the M.P.E.P., "[a] statutory process is one that requires the measurements of physical objects or activities to be transformed outside of the computer into computer data,

where the data comprises signals corresponding to physical objects or activities external to the computer system, and where the process causes a physical transformation of the signals which are intangible representations of the physical objects or activities." (*Emphasis added*) Examples provided by the M.P.E.P. of this type of claimed statutory process include the following:

> A method of using a computer processor to analyze electrical signals and data representative of human cardiac activity by converting the signals to time segments, applying the time segments in reverse order to a high pass filter means, using the computer processor to determine the amplitude of the high pass filter's output, and using the computer processor to compare the value to a predetermined value. In this example the data is an intangible representation of physical activity, i.e., human cardiac activity. The transformation occurs when heart activity is measured and an electrical signal is produced. This process has real world value in predicting vulnerability to ventricular tachycardia immediately after a heart attack.
>
> A method of using a computer processor to receive data representing Computerized Axial Tomography ("CAT") scan images of a patient, performing a calculation to determine the difference between a local value at a data point and an average value of the data in a region surrounding the point, and displaying the difference as a gray scale for each point in the image, and displaying the resulting image. In this example the data is an intangible representation of a physical object, i.e., portions of the anatomy of a patient. The transformation occurs when the condition of the human body is measured with X-rays and the X-rays are converted into electrical digital signals that represent the condition of the human body. The real world value of the invention lies in creating a new CAT scan image of body tissue without the presence of bones.
>
> A method of using a computer processor to conduct seismic exploration, by imparting spherical seismic energy waves into the earth from a seismic source, generating a plurality of reflected signals in response to the seismic energy waves at a set of receiver positions in an array, and summing the reflection signals to produce a signal simulating the reflection response of the earth to the seismic energy. In this example, the electrical signals processed by the computer represent reflected seismic energy. The transformation occurs by converting the spherical seismic energy waves into electrical signals which provide a geophysical representation of formations below the earth's surface. Geophysical exploration of formations below the surface of the earth has real world value.

Further, according to the M.P.E.P., "If a claim does not clearly fall into one or both of the safe harbors, the claim may still be statutory if it is limited to a practical application in the technological arts." (*Emphasis added*)

As discussed in greater detail below, the claims of the present invention do more that merely manipulate data. Independent claim 128 defines a method for identifying a culture medium component that comprises, in part:

...

determining a property, having an indicia, of the plurality of first culture media;

measuring the indicia of the property of the plurality of first culture media;

determining a relationship between the measured indicia of the property, and at least one parameter of the first test compounds;

calculating an estimated indicia for each first culture media in the first test library using the determined relationship;

setting a test requirement having a test indicia range;

selecting a second test library comprising at least one second culture medium having at least one respective second test compound, wherein each second culture medium is a first culture medium having an estimated indicia that satisfies the test requirement;

measuring the indicia of the property of the at least one culture medium; and

identifying one second culture medium having a measured indicia that satisfies the test requirement.

One aspect of the invention defined by independent claim 128 is directed to identification of culture medium components, using bioinformatics technology. Scientists, for example, "construct a first test library," which entails identification of culture media from which initial screening assays can be conducted. The culture media can have various properties that are measurable through the screening assays. The scientist then determines a property that is of interest for a particular research or study. Subsequently, the indicia (or quantitative value) of the property is measured by assaying the culture media. A relationship is determined, usually by a

computer-based methodology, to develop a model that correlates the measured indicia of the property to at least one parameter of the first test compounds. Using this relationship, it is then possible to calculate an estimated indicia for all of the culture media in the first test library. Moreover, the scientist may set a test requirement, which would enable them to identify only the most desired candidate culture media for further screening. From this information, a second test library can be selected. Finally, the activity of the second test compounds is measured, again by assaying or other known methods. Second culture media that actually have the required indicia level are then identified. Further, at least a portion of this information can be output to a display device for visual examination and/or analysis, or transferred to a storage device for further access and/or manipulations.

As can be seen, the claimed invention involves multiple steps that are performed outside of the computer. At least one of these steps is dependent on certain data manipulations performed by the computer. For example, the relationship determined by the computer can be used to estimate the indicia of culture media that have not yet been assayed. This greatly reduces the experimentation time and costs associated with testing culture media, particularly where large quantities are involved. Using the estimated values of the indicia, only a reduced set of culture media need be tested.

It has been found that the amount of actual experimentation can be significantly reduced using the method claimed in the present invention. The identification of a component that is useful in producing a particular property in a culture medium has typically required extensive experimentation. As discussed in the "background" section of the application, previous attempts to improve culture media have largely relied on ad hoc, trial-and-error techniques. There was a lack of systematic and predictive methods for identifying components to improve cell performance in culture, as well as high throughput methods for identifying medium components. However, the methodology set forth in the present invention can significantly reduce the amount of actual experimentation required to identify culture media having the desired property. In fact, the present invention has been used to identify a number of culture medium components having a

desired property. The present invention contains several known components working synergistically to quickly identify novel compounds while containing cost levels.

Applicants respectfully submit that independent claim 128 provides a tangible result outside of the computer.

It is therefore respectfully submitted that claims 2-15, 18-30, and 128 fully satisfy the requirements of 35 U.S.C. §101.

IV. Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-15 and 18-30 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. In support of this rejection, the Examiner principally identifies that, in claim 1, a relationship is determined but without connection or definition of cooperativity between measured first indicia in order to define either the "relationship" in claim 1.

Applicants have reviewed and made amendments to the claims that should remedy all instances of indefiniteness. For example, claim 1 has been cancelled and respectively replaced with claim 128. The steps performed in claim 128 have been worded to better describe the connection and cooperation between various elements.

It is therefore respectfully submitted that all of the pending claims satisfy the requirements of 35 U.S.C. §112, second paragraph. Withdrawal of this rejection is respectfully requested.

V. Informalities

The Examiner objected to claims 3, 5, and 8-10 by stating that the parameters wherein subscripts are present are printed with too small of a font to read them clearly. Applicant has amended claims 3, 5, and 8-10 to correct the noted informality.

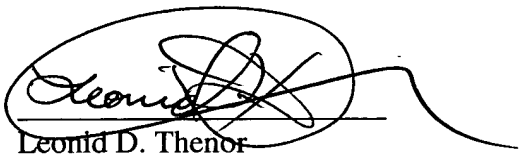
Withdrawal of this rejection is respectfully requested.

Authorization

The Commissioner is hereby authorized to charge any additional fees that may be required for this Response, or credit any overpayment, to deposit account number 08-0219.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of which is required to make this response timely, and is hereby authorized to charge any fee for such, to deposit account number 08-0219.

Respectfully submitted,



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